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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/894,921 | 06/28/2001 | Udit Batra | 20243CA | 1812 |
| 210 | 7590 | 05/23/2005 | EXAMINER | |
| MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907 | | | SHARAREH, SHAHNAM J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/894,921

Applicant(s)

BATRA ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 48-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 48-53, 55, 57-63 and 65-68 is/are rejected.
- 7) ☒ Claim(s) 54, 56 and 64 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment filed on February 24, 2005 has been entered. Claims 1, 48-68 are pending.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 48-53, 55, 57-63, 65-68 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Makooi-Morehead US Patent 6,238,695 in view Remington: the Science and Practice of Pharmacy 19th edition (pages 1616-1620) (IDS, filed June 28, 2001 or Phipps US Patent 5,260,073 for the reasons of record.

Response to Arguments

Applicant's arguments filed on February 24, 2005 have been fully considered but they are not persuasive. As has previously discussed on the record, Applicant argues that Makooi does not teach the instant amount of superdisintegrant. (Arguments at pages 5).

In response, Examiner reiterates his position that the issue disputed here is not whether Makooi uses superdisintegrants in amounts of 1-5 wt%, rather, whether the scope of the instant claims are limited to such range. Examiner has previously reasoned that applicant's position is based on an illusory distinction between the scope of the instant disintegrants and superdisintegrants, because neither the specification nor the art draws a distinction between the scope of the instant disintegrant and superdisintegrants. (see Final Rejection filed on June 7, 2004).

Art Unit: 1617

Applicant's assertion that Phipps reference does not teach HIV antivirals and thus is not combinatble with Makooi is noted but is not persuasive. The Phipps reference was only submitted in the previous Office Action to elaborate how the state of art characterizes superdisintegrants and disintegrants? Accordingly, it was concluded that superdisintegrants and disintegrants are viewed to be art recognized functional equivalents. See for example Phipps at col 8, lines 59-64 or Remington at page 1619. Note that croscarmellose is expected to provide similar function as alginic acid or microcrystalline cellulose. Thus, even the state of art appears to view the difference between the superdisintegrants and disintegrants ito be illusory.

Finally, Applicant argues that even though Makooi teaches the use of superdisintegrants in amounts of 1-10wt% in the art, such teachings is not an embodiment of the invention being claimed by Makooi (see Arguments at page 7, 2rd para.). In response, Examiner reiterates his previous position that Makooi's teachings are not a direct teaching away from the instant claims.

Applicant further argues that Makooi teaches away from using superdisintegrants in amounts of about 1-10%. In response, Examiner states that in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the results sought by the applicant." *In re Gurley*, 31 USPQ2d 1130, 1131-2 (Fed. Cir. 1994). Here, the mere fact that Makooi teaches an alternative means of improving drug delivery, as described by higher concentrations of superdisintegrants in his composition, does not preclude optimization of the amounts of superdisintegrant. Further there is no direct statement that low levels

Art Unit: 1617

of superdisintegrants would not be suitable with efavirnez. Thus, applicant's arguments are not persuasive.

Declaration Under 37 CFR 1.132

Upon further review of the evidence, Examiner finds the Declaration under 37 CFR 1.132 filed on October 2003 to be sufficient to overcome the rejection of claims 54, 56, and 62 based upon the results described in paragraphs 13-19 of the Declaration and the reasons set forth in the Office Action mailed on June 7, 2004. The Declaration provides a showing of unexpected improvement of the bioavailability of efavirnez tablets when about 5% of croscarmellose is employed in the instantly claimed combination of ingredients. However, the declaration is not commensurate with the scope of all other pending claims.

Claim Objection

Claim 54, 56, 62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, because the scope of such .

Allowable Subject Matter

Claim 54, 56, 62 are free of art in view of the unexpected results presented in the declaration under 37 CFR 1.132 filed on Oct 06, 2003.

Claim 54, 56, 62 would be allowable if rewritten or amended to overcome the objection, set forth in this Office action.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

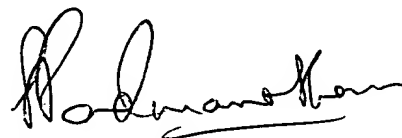
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER